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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/445,154	03/06/00	WILLIAMS	S 1348.017 USU

IM22/0910  
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EXAMINER	
OLSEN, K	
ART UNIT	PAPER NUMBER

1744 7

DATE MAILED: 09/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/445,154	WILLIAMS ET AL.
	Examiner Kaj Olsen	Art Unit 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 06 March 2001.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.                    6) Other: \_\_\_\_\_.

**DETAILED ACTION**

*Specification*

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

*Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The inventors did not sign the declaration with both a family and given name as required 37 CFR 1.63(a3).

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 specifies the presence of a conductive layer provided "in two parts". This causes confusion later on in claim 1 when other layers are specified as being over the conductive layer

in particular locations. The examiner recommends the applicant instead explicitly recite the presence of two electrodes formed and refer to the various addition layers with respect to these electrodes (when relevant) and not to the layer as a whole.

In claim 2, the apparent negative limitation with regard to the absence of filler should be rephrased in more precise language (e.g. --where the reagent does not contain filler....--).

It is unclear how claims 4 and 10 further limit claim 1 or claim 2 because claim 1 already specified the mesh was coated with a surfactant.

Claims 6, 7, 12, and 13 call for the presence of both graphite and carbon particles. However, graphite is a form of carbon particle making it unclear if the carbon refers to the same or a different form of carbon. Although the examiner is aware that there are other forms of carbon other than graphite, applicant has not specified in the claims and specification what that form of carbon might be rendering these claims unclear.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 4, 8, 10, and 14 are rejected under 35 U.S.C. 102(b) or 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carter et al (5,628,890).

Carter teaches an electrochemical device which comprises a non-conductive substrate 1, a conductive layer (2-5, and 5a) which has a gap for facilitating the electrochemical analysis (fig. 1). Carter further teaches an analyte specific reagent (8, 8a), a reference electrode (6a-6c), a spacer layer (either 7 or the lower layer 11), a monofilament mesh (9 or 10) coated with a surfactant (col. 5, lines 12-26) and laid over the reagent (fig. 1), and a second non-conductive layer (11 and/or 13). It would appear the second non-conductive layer is not coextensive with the mesh (fig. 1) and provides a sample application area at one edge of the mesh giving the claim language it's broadest reasonable interpretation. Aperture 12 defines a portion not coextensive with element 10 while aperture 14 defines a portion of 13 not coextensive with 10. 12 is off to one edge of 10 (fig. 1) while 14 is off to one edge of 10 (i.e. the aperture is off to one edge of the raised portion shown in fig. 1a).

Alternatively, although Carter does not show drawings having the apertures at the furthest end, Carter teaches that aperture 14 should be at the end most remote from electrode 6b and should not expose any of the electrodes (col. 6, lines 28-36). In view of these suggestions, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to place the aperture at the extreme end of the mesh material to ensure the aperture does not expose the electrodes and places the aperture as far from the reference electrode as desired.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter ('890) in view of Hill et al (5,820,551).

Carter teaches all the limitations of the claims, but does not teach the use of glucose dehydrogenase. Carter utilizes glucose oxidase. Hill teaches that both glucose oxidase and glucose dehydrogenase are both known in the art as suitable enzymes for electrodes (col. 4, line 42). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Hill for the device of Carter because the art recognized that glucose dehydrogenase was a suitable alternative enzyme for the sensing of glucose.

Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter ('890) in view of Durst et al (6,248,596).

Carter sets forth all the limitations of the claim, but does not explicitly teach the presence of a cell lytic agent. Carter does set forth that it is useful to perform a cell lysis step in order to remove red blood cells interference (col. 1, lines 20-29). Durst teaches that cell lysis in electrochemical sensors can be achieved by the addition of cell lytic agents to the sensor itself

(paragraph bridging col. 13 and 14). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a cell lytic agent as taught by Durst for the sensor of Carter in order to remove interference from cells in the sample without requiring a preliminary sample preparation.

Claims 6, 7, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter ('890) in view of Maley et al (5,770,028) and Johnson et al (5,429,735).

Carter sets forth all the limitations of the claims, but does not disclose the claimed combination of graphite, carbon, and polymer for the conductive layer. Johnson teaches the use of an ink for glucose sensors which comprises a combination of carbon black and graphite particles (col. 2, lines 21-23). Although Johnson doesn't explicitly set forth a polymer binder, it is conventional in the art to utilize a binder in conjunction the conductive ink (in the absence of a binder, nothing will hold the conductive particles together). In particular, Maley teaches the use of a resin binder in conjunction with the conductive carbon particles for an ink (col. 15, lines 31-34). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the combined teachings of Johnson and Maley for the electrode of Carter because the combination of graphite and an additional form of carbon has been found to be an effective electrode for blood glucose sensing. With respect the claimed particle sizes and surface areas, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the set forth ranges. Maley teaches that it is known to control the carbon particle sizes in order to control the quality of the electrode (col. 14, lines 41-50; and col. 15, lines 6-10). Because it is known in the art to control particle sizes, since it has been held that

where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 8:00 AM-5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for this Group is (703) 305-7719.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

Kaj K. Olsen, Ph.D.



Patent Examiner

AU 1744



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